11-15-06

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Mail Stop Appeal Brief-Patents **TRANSMITTAL FORM** *(To be used for all correspondence after initial filing)*		Application Number	09/670,781
		Filing Date	September 27, 2000
		Confirmation Number	6751
		Inventor(s)	DALY
		Group Art Unit	1761
Express Mail Label No.: EV 196253545 US		Examiner	Weinstein, S.
Total Number of Pages in This Submission:	38	Attorney Docket No.	00-39 RCE 1

ENCLOSURES *(check all that apply)*

- ☒ Fee Transmittal Form *(submit in duplicate)*
  - ☐ Fee Attached $
  - Check No.:
- ☐ Amendment / Response
  - ☐ After Final
- ☐ Affidavits / Declaration(s)
- ☐ Extension of Time Request
- ☐ Information Disclosure Statement
  - ☐ Form PTO-1449
  - ☐ Cited References
  - ☐ Search report
- ☐ Drawing(s): Number of Pages _____ Number of Figs. _____ and cover sheet
  - ☐ Formal
  - ☐ Informal
- ☐ Assignment Papers
  - ☐ Cover Sheet
- ☐ Drawing Change Authorization Request and Amended Figure(s)
- ☐ Request for Return of PTO-1449 Forms
- ☐ Petition to the Commissioner
- ☐ To Convert a Provisional Application
- ☐ Power of Attorney, Revocation Change of Address
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- ☒ Certificate of Mailing by Express Mail
- ☐ Issue fee Transmittal Form PTOL-85(b) + (c) and Cover Sheet
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☒ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- ☐ Request for Continued Examination (RCE)
- ☐ Status Request Letter
- ☐ Small Entity Statement
- ☐ Request for Refund
- ☐ Response to Missing Parts / Incomplete Application
- ☐ Other Enclosure(s): _____

Current Due Date: November 13, 2006 (November 12, 2006 = Sunday)

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Individual and Company	Timothy A. Nathan, Reg. No. 44,256 RESPIRONICS, Inc., 1010 Murry Ridge Lane, Murrysville PA, 15668
Signature	
Date	November 13, 2006

CERTIFICATE OF MAILING

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Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date: November 13, 2006,
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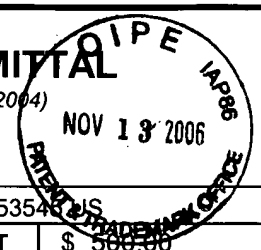
Typed Name	Timothy A. Nathan, Reg. No. 44,256		
Signature		Date	November 13, 2006

FEE TRANSMITTAL

(Effective 12/08/2004)



Application Number	09/670,781
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First Named Inventor	DALY
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"Express Mail" Label No. EV 196253546 US

TOTAL AMOUNT OF PAYMENT | $ ~~500.00~~

METHOD OF PAYMENT

1. ☒ The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Deposit Account Number: 50-0558

Deposit Account Name: Respironics, Inc.

☒ Charge any additional fee required under 37 C.F.R. §§ 1.16, 1.17 1.19 and 1.20

☐ Charge the Issue Fee set forth in 37 C.F.R. § 1.18

2. ☐ Payment Enclosed:

Check (Check No. _____)

FEE CALCULATION *(fees effective 12/08/2004)*

1. BASIC FILING, SEARCH, AND EXAM FEES

(Large Entity Only)

Appln. Type	Filing Fee($)	Search Fee($)	Exam Fee($)	Fees Paid
Utility	300	500	200	
Design	200	100	130	
Plant	200	300	160	
Reissue	300	500	600	
Provisional	200	0	0	

SUBTOTAL (1) $ 0.00

2. CLAIMS

			Extra Claims		Fee from Below	Fee Paid
Total Claims	___	- ___ *	___	x	50 =	
Ind. Claims	___	- ___ *	___	x	200 =	
Multiple Dependent Claims add					360 =	

* Enter Highest Number Previous Paid For

Large Entity Fee ($)	Small Entity Fee ($)	Fee Description
1202 50	2202 25	Claims in excess of 20
1201 200	2201 100	Independent claims in excess of 3
1203 360	2203 180	Multiple dependent claim
1204 200	2204 100	Reissue independent claims over original patent
1205 50	2205 25	Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) $ 0.00

FEE CALCULATION *(continued)*

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 for each additional 50 sheets or fraction thereof. See 35 U.S. C. § 41(a)(1)(G) and 37 C.F.R. § 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 fraction thereof	Fee($)	Fee Paid($)
_____	-100 = _____	/50 = _____ (round up to a whole number)	X 250	= 0.00

4. ADDITIONAL FEES

Large Fee Code	Entity Fee ($)	Small Fee Code	Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or declaration	
1811	100	1811	100	Certificate of Correction	
1812	2,520	1812	2,520	For filing a request for reexamination	
576	25	576	25	Additional filing receipt, duplicate or corrected due to applicant error	
1251	120	2251	60	Extension for response within first month	
1252	450	2252	225	Extension for response within second month	
1253	1,020	2253	510	Extension for response within third month	
1254	1,590	2254	795	Extension for response within fourth month	
1255	2,160	2255	1,080	Extension for response within fifth month	
1401	500	2401	250	Notice of Appeal	
1402	500	2402	250	Filing a brief in support of an appeal	500.00
1403	1,000	2403	500	Request for oral hearing	
1452	500	2452	250	Petition to revive unavoidably abandoned application	
1453	1,500	2453	750	Petition to revive unintentionally abandoned application	
1501	1,400	2501	700	Utility issue fee (or reissue)	
1502	800	2502	400	Design issue fee	
1814	130	2814	65	Statutory Disclaimer	
1460	130	1460	130	Petitions to the Director	
1807	50	1807	50	Petitions related to provisional applications	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of property)	
1801	790	2801	395	Request for Continued Examination	
1504	300	1504	300	Publication Fee	
Other Fee (specify) _____					

SUBTOTAL (3) $ 500.00

SUBMITTED BY

Typed or Printed Name	Timothy A. Nathan			Reg. Number	44,256
Signature		Date	November 13, 2006	Deposit Account Number	50-0558

Certificate of Mailing by "Express Mail"

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November 13, 2006
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Timothy A. Nathan
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

Inventor	:	DALEY
Appln. No.	:	09/670,781
Conf. No.:	:	6751
Filed:	:	September 27, 2000
Title:	:	SYSTEM, METHOD AND PACKAGE FOR PROVIDING A LIQUID SOLUTION
Group Art Unit	:	1761
Examiner	:	WEINSTEIN, S.
Docket No.	:	00-39 RCE 1

* * * * *

November 13, 2006

APPEAL BRIEF

Mail Stop Appeal Brief - Patent
Commissioner for Patents and Trademarks
Alexandria, VA 22313-1504

Sir:

Pursuant to 35 U.S.C. § 134 and 37 C.F.R. § 41.37, entry of this Appeal Brief in support of the Notice of Appeal filed September 12, 2006 is requested. This Brief is filed on November 13, 2006 within the two-month deadline (November 12, 2006 falls on Sunday). This submission sets forth the authorities and arguments upon which Applicant relies in support of the appeal from the final rejection of claims 1-4, 6, 7, 10, 12, 13, 15-17, and 18-39 in the Office Action dated March 13, 2006 of the above-identified patent application. The fee under 37 C.F.R. § 41.20(b)(2) in the amount of $500 is included with this submission.

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

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Express Mail Label No. EV196253545 US .

Timothy Nathan, Reg. No. 44,256

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest in the above-identified patent application is RIC Investments, LLC as the assignee which was recorded on October 18, 2005 at reel/frame: 016653/0709. RIC Investments, LLC is a subsidiary of Respironics, Inc.

II. RELATED APPEALS AND INTERFERENCES

There is no other appeal or interference that will directly affect, or be directly affected by, or have any bearing on the Board's decision with regard to this Appeal.

III. STATUS OF THE CLAIMS

Claims 1-4, 6, 7, 10, 12, 13, 15-17, and 19-39 are pending in the application, and are being appealed. Claims 5, 8, 9, 11, 14, and 18 were cancelled.

IV. STATUS OF THE AMENDMENTS

The claims were last amended in the Response and Amendment filed May 4, 2006 in which claims 23-39 were added. The Office Action dated July 13, 2005 indicates that these amendments were entered. No amendments were filed subsequent to a final rejection. Therefore, the claims in the "Claims Appendix" of this Appeal Brief are the current version of the claims.

V. SUMMARY OF CLAIMED SUBJECT MATTER

An embodiment of the claimed subject matter, as recited in claim 1, is shown in Fig. 1 and described at p. 4, ll. 12-30. This embodiment is a packaged solution having a cup-shaped container (10) that is shaped to have a width that is greater than the depth and has a cavity (12) which opens to a mouth (16). Disposed inside the container is a volume of a solution (18) that comprises sucrose and water. Specifically, the solution (18) comprises about 10% to about 50% sucrose while the remainder of the solution (18) is water. The container is sealed with a

cover (20) disposed over the mouth (16). Both the solution (18) and an interior of the container (10) are in an aseptic state.

Another embodiment of the invention, as recited in claims 12 and 17, is shown in Fig. 3 and described at p. 6, ll. 5-13. This embodiment is a method for providing a solution (18) for use in conjunction with a planned medical procedure on a neonatal infant. The method includes preparing the solution (18) comprising sucrose and water, packaging the solution (18) in single-use containers (10), assembling a plurality of the single-use containers (10) in a shipping container (30), and shipping the shipping container (30), shown in Fig. 2, to an intended site of usage of the solution (18). Next, the method includes opening an individual, single-use container (10) of the solution (18) prior to the planned medical procedure, administering a selected volume dose of the solution (18) orally to the neonatal infant, and discarding any residual solution (18) within the opened, individual, single-use container (18) after the planned medical procedure.

Yet another embodiment of the claimed subject matter, as recited in claims 23 and 29, is shown in Fig. 1 and described at p. 4, ll. 12-30. This embodiment includes a packaged solution for use in conjunction with a medical procedure performed on an infant. The packaged solution includes a cup-shaped container (10) having a width that is greater than the depth defining a cavity (12). The container also has an inner surface and opens to a mouth (16) so that an object such as a pacifier may be inserted into the container. The cup-shaped container (10) also includes a flange (14) extending outwardly about the mouth (16). In claim 23, the container (10) is made from a polymeric material. A volume of a solution (18) comprising sucrose and water is disposed within the cavity (12). In claim 23, the solution is approximately 24% sucrose and 76% water. In claim 29, the solution is between 10% and 50% sucrose. A cover (20) is disposed over the mouth (16) to seal the solution (18) within the cavity (12). The cover seals at least a portion of the top surface of the flange (14) and has a tab (14b) extending beyond the periphery of the flange (14) such that the user can easily grasp and remove the cover (20).

The final embodiment of the present invention, as recited in claim 37, is shown in Fig. 3 and described at p. 6, ll. 5-13. This embodiment is a method of producing a packaged solution assembly for use in conjunction with a medical procedure on an infant. This method

includes the steps of providing a cup-shaped container (10) having a width sized to receive at least a portion of an object therein. The cup-shaped container (10) defines a cavity (12) that opens to a mouth (16) and a flange (14) that extends about the mouth (16) of the cavity (12). The next step of this method includes mixing between 10% to 50% sucrose with water to create a sucrose solution (18), transferring the sucrose solution (18) into the cavity (12) of the container (10), and then sealing the container (10) with a cover (20) that is placed over the mouth (16) and sealed with the flange (14) of the container (10).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Two issues are presented for review in this Appeal:

Whether claims 1-4, 6, 7, 10, 21, and 23-36 are patentable under 35 U.S.C. § 103(a) over U.S. Patent No. 4,054,207 to Lazure et al. in view of the Applicant's admission of the prior art as evidenced by the Blass et al. article, the Stevens et al. article dated 1997 ("the Stevens 1997 article"), the Stevens et al. article dated 1999 ("the Stevens 1999 article"), the Franck article, further in view of U.S. Patent No. 3,654,746 to Beckers, and U.S. Patent No. 4,597,242 to Hendriks et al., U.S. Patent No. 4,211,338 to Bublitz, further in view of the Seattle Post-Intelligencer article, Wisconsin State J. article, further in view of the San Francisco Examiner article, New Food Products in Japan article, Food Engineering article, further in view of U.S. Patent No. 2,138,241 to Koch et al., U.S. Patent No. 4,165,594 to Corbic, U.S. Patent No. 4,875,620 to Lane, U.S. Patent No. 5,429,262 to Sharkey, U.S. Patent No. 3,390,766 to Stockdale, U.S. Patent No. 3,478,489 to Meisner, and U.S. Patent No. 3,414,414 to Christine et al.; and

Whether claims 12, 13, 15-17, 19, 20, 22, and 37-39 are patentable under 35 U.S.C. § 103 over the applicant's admission of the prior art as evidenced by the Blass et al. article, the Stevens et al. article dated 1997 ("the Stevens 1997 article"), the Stevens et al. article dated 1999 ("the Stevens 1999 article"), the Franck article, the Seattle Post-Intelligencer article, the Wisconsin State J. article, in view of U.S. Patent No. 4,054,207 to Lazure et al. further in view of U.S. Patent No. 3,654,746 to Beckers, and U.S. Patent No. 4,597,242 to Hendriks et al.,

U.S. Patent No. 4,211,338 to Bublitz, further in view of U.S. Patent No. 2, 138,241 to Koch et al., U.S. Patent No. 4,165,594 to Corbic, U.S. Patent No. 4,875,620 to Lane, U.S. Patent No. 5,429,262 to Sharkey, U.S. Patent No. 3,390,766 to Stockdale, U.S. Patent No. 3,478,489 to Meisner, and U.S. Patent No. 3,414,414 to Christine et al., and further in view of the San Francisco Examiner article, New Food Products in Japan article, Food Engineering article.

VII. ARGUMENT

As indicated above, the issue presented for review in this appeal is whether the pending claims are patentable under 35 U.S.C. § 103. It is generally accepted that a prima facie case of obviousness is established when an examiner can provide: 1) one or more references, 2) that were available to the inventor, 3) which teach each and every limitation of the claims, 4) and a suggestion to combine or modify the references, 5) the combination or modification of which would appear to be sufficient to have made the claimed invention obvious to one of ordinary skill in the art. Once the prima facie case has been made, it is then left to the applicant to rebut the prima facie case. In re Oetiker, 977 F.2d 1443, 24 U.S.P.Q.2d 1443, 1447 (Fed. Cir. 1992). Although the Examiner has set forth two separate grounds of rejection, the Examiner's remarks concerning these rejections have been consolidated and discussed together in the Office Actions. The Applicant's arguments in this Brief regarding the patentability of the claims will also focus on the features common to the claims in both rejections, and will thus be discussed together as well.

A. The pending claims are patentable under 35 U.S.C. § 103 because the supplemental references utilized by the Examiner were not from within the inventor's field of endeavor or reasonably pertinent to the problem sought to be solved.

The C.C.P.A. stated that when resolving the question of obviousness, we presume full knowledge by the inventor of all the prior art in the field of his endeavor. In re Wood, 599 F.2d 1032, 202 U.S.P.Q.2d 1767, 1773 (C.C.P.A. 1979). With regard to

prior art outside the field of endeavor, we only presume knowledge from those arts reasonably pertinent to the particular problem with which the inventor was involved. Id.

In the last Office Action, the Examiner stated that "[i]f 'the problem' is inconvenience, and the potential for waste and contamination, these issues are those that are universally recognized as being addressed by single-use/serve containers." (See, e.g., Office Action of March 13, 2006 at p. 3, ll. 3-6.) From this statement, it appears that the Examiner determined that the relevant art, or field of endeavor, was the container or packaging art. Once so concluded, it does, in theory, seem plausible that one of ordinary skill in the container art would recognize that various foods and/or medications can be stored in single-use/serving containers. However, the field of endeavor for the inventor of the present invention was children's medical devices and not containers.

One of ordinary skill in the children's medical device art would not be likely to reference the container art to find an answer to the problem at hand. This begs the question: what was the problem that the inventor sought to solve? The problem was that doctors were not using sucrose even though sucrose was known to alleviate the suffering and distress of neonates enduring painful medical procedures in neonatal intensive care units as fully described in the Blass article. For those doctors that chose to implement this procedure, the state of the art was to hand-mix sucrose in an on-site kitchen or pharmacy. However, may physicians would simply forgo using sucrose altogether. (Physician's Declarations, Evidence Exhibit C.) It is not obvious that the solution to the problem of physicians not utilizing this procedure would be found by referencing the container art. If anything, the Examiner's conclusion appears to be based upon improper hindsight. Of course, once the problem has been identified and a solution presented, all inventions appear obvious in hindsight. The relevant art, or field of endeavor, for the present invention was children's medical devices. It would not be obvious for one of ordinary skill in the children's medical device art to reference the container art to find a solution to the problem solved by the present invention. Accordingly, the Examiner's rejection is improper for imputing the inventor with

knowledge outside the inventor's field of endeavor or reasonably pertinent to the problem sought to be solved.

B. The pending claims are patentable under 35 U.S.C. § 103 because the the prior art of record lacks any suggestion to modify or combine the references as proposed by the Examiner.

It is well settled that when a combination of references are relied upon to establish a prima facie case of obviousness there must be a suggestion or motivation, either in the references or in the knowledge generally available to one of ordinary skill in the art, to combine the reference teachings, and that suggestion or motivation must be found in the prior art, not in an applicant's disclosure. In re Vaeck, 947 F.2d 488, 495, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991) ("the prior art . . . offers no suggestion, explicit or implicit, of the substitution that is the difference between the claimed invention and the prior art.")

The analysis for determining whether, in a particular situation, there is a proper suggestion or motivation to combine references is discussed in detail at M.P.E.P. § 2143.01. There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. In re Rouffet, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1453, 1457-58 (Fed. Cir. 1998) (The combination of references taught every element of the claimed invention, however, without a motivation to combine, a rejection based on a prima facie case of obviousness was held improper.)

In the present Application, the Examiner has taken the position that obviousness has been established by presenting references that show sucrose is useful as an analgesic for newborns and supplements these references with other references that describe the use of single-use/single-serve containers. (See, e.g., Office Action of March 13, 2006 at p. 3, ll. 3-6). The Applicant contends that what is lacking in the Examiner's rejections is any suggestion or motivation to combine these references as proposed by the Examiner.

Passage of time exhibits a trend away from the present invention

The Federal Circuit has held that it is proper to consider the "trend" in the art to show the obviousness of the inventor's solution. Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH, 139 F.3d 877, 45 USPQ2d 1977 (Fed. Cir. 1998). In this case, there is a trend away from the present invention. The Lazure et al. reference was filed in 1976 and the Blass et al. article was submitted for publication in 1989. The Examiner claims that the Applicant's invention is obvious to one of ordinary skill in the art, and yet is unable to present any reference that suggests the proposed modification or combination. Hospitals and pharmacies, even though they were aware of the analgesic effect of sucrose, have chosen to hand-mix analgesic agents and subject newborn infants to potentially inconsistent and unsanitary solutions. This, if anything, exhibits a trend away from the present invention. It defies logic to conclude that these skilled health care providers would continue utilizing an inefficient and potentially hazardous process if there was an "obvious" solution.

Recognition of the source of the problem exhibits patentability

As articulated by the C.C.P.A., "a patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 USC 103." In re Nomiya, 509 F.2d 566, 184 U.S.P.Q. 607, 612 (C.C.P.A 1975).

As outlined in the background of the present Application, the state of the art was to hand-mix these solutions in an on-site kitchen or pharmacy. (Applicant's Application at p. 2, ll. 25-27.) Unfortunately, many doctors would forgo using sucrose and needlessly subject distressed infants to further suffering. (Physician's Declarations, Evidence Exhibit C). The problem sought to be solved by the Inventor was the lack of sucrose use by physicians and nurses with distressed infants in neonatal intensive care units. The source of the problem was one or more of several issues including: the time involved in mixing the solution, the inconsistency of hand-mixed solutions, the potential for contamination, and the difficulty of applying the solution to a pacifier. Recognizing the source of the problem, the Inventor proposed an elegant solution

as recited in the claims of the present Application. The solution was to package a sucrose solution manufactured with a consistent concentration in a sterile container dimensioned so that a pacifier or other object may be easily inserted into the container. The art did not recognize the source of the problem. As such, the art could not propose the unique solution disclosed and claimed in the present Application.

The trend in the art and failure of the art to even recognize the problem indicates that there is no suggestion or motivation to combine the references as proposed by the Examiner. To the contrary, the art taken as a whole teaches away from the present invention. Accordingly, the Examiner has not met his burden of presenting a prima facie case of obviousness. As such, the pending claims are patentable over the prior art of record.

C. The pending claims are patentable under 35 U.S.C. § 103 because the Examiner failed to properly consider the Applicant's evidence of commercial success, long-felt but unresolved need, and copying by a competitor.

Even if an examiner establishes a prima facie case of obviousness, the burden shifts to the applicant to rebut the examiner's case with objective evidence of nonobviousness. An applicant may present evidence relating to any of the secondary considerations outlined in Graham v. John Deere Co., 381 U.S. 1, 148 U.S.P.Q. 459 (1966) such as commercial success, fulfilling a long-felt need, failure of others, copying by others, and unexpected results. In addition, later opinions have added additional secondary considerations such as later discovered unexpected properties of the claimed invention, licenses or industry acquiescence, and skepticism prior to invention by those of ordinary skill. In re Mayne, 104 F.3d 1339, 41 U.S.P.Q.2d 1451 (Fed. Cir. 1997); Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 119 F.3d 953, 43 U.S.P.Q.2d 1294, 1297 (Fed. Cir. 1997); In re Dow Chem. Co., 837 F.2d 469, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1988). As noted by the Federal Circuit, "evidence of secondary considerations may often be the most probative and cogent evidence in the record." In re Piasecki, 745 F.2d 1468, 223 U.S.P.Q. 785, 790 (Fed. Cir. 1984).

The Applicant sells an embodiment of the invention disclosed and claimed in the present Application under the trademark SWEET-EASE™ (Evidence Exhibit A). This product has met with surprising commercial success, resolves a long-felt and unresolved need in the industry, and has been copied by at least one competitor.

Surprising Commercial Success

As outlined in the Declaration of Cathy N. Bush (Evidence Exhibit B), the SWEET-EASE™ product has had surprising commercial success. Ms. Bush compares the SWEET-EASE™ product with the HEEL HUGGER™ product. Both products are disposable, single-use products used on infants and sold by the Applicant. Even though the SWEET-EASE™ product has been in the industry for less than half as long, it achieved approximately six times as many sales in 2003. Ms. Bush attributes the surprising commercial success of the SWEET-EASE™ product to the fact that it provides a convenient, aseptically packaged container filled with a sucrose solution not previously available in the medical industry.

During prosecution, the Examiner stated that "it is not clear how effective the latter is in providing pain relief to a newborn." (Office Action of January 5, 2005 at p. 3, l. 22 – p. 4, l. 1). This conclusion, however, misses the mark. The sales data of the HEEL HUGGER™ product was not entered to demonstrate the surprising results of the SWEET-EASE ™ product from a technical perspective; it was entered to show the surprising commercial success of the SWEET-EASE™ product. The sales data of the HEEL HUGGER™ product was merely included as a baseline for comparison with the sales of the SWEET-EASE™ product. The surprising commercial success of the SWEET-EASE™ product is persuasive evidence of the non-obviousness of the claimed invention which must be considered by the Examiner.

Long-felt, Unresolved Need

The present invention fulfills a long-felt need in the industry. As described in the declarations of Don T. Granger, M.D., Neal Guttenberg, M.D., and M. David Yohannan, M.D. (Physician's Declarations, Evidence Exhibit C), hand-mixing sucrose solutions have been

undesirable. The state of the art was to hand-mix these solutions in an on-site kitchen or pharmacy; yet, hand-mixing may contaminate the solution, result in wasted time, and the creation of inconsistent solutions. As noted in these declarations, physicians would simply try to consol the infants rather than use sucrose. Accordingly, it is clear that the present invention addresses a problem that has defied resolution. The Physicians' Declarations describe the state of the art before introduction of the SWEET-EASE ™ product and the long-felt need of neonatologists for a solution to this problem.

The Examiner concluded that "the long felt need showing does not outweigh the strong case of prima facie obviousness. The aseptic, individual sucrose solutions provide convenience and safety. However, this is the same advantage that any aseptic medicinal or food provides the user." (Office Action of January 5, 2005 at p. 4, ll. 14-15.) This analysis seems similar to the analysis criticized by the Federal Circuit in Piasecki. In this case, the Federal Circuit stated that "[u]nder the Board's approach the prima facie case took on a life of its own, such that each fact presented in rebuttal, when it was evaluated at all, was evaluated against the conclusion itself rather than against the facts on which the conclusion was based." Id. at 788. Based on the Examiner's remarks it is difficult to determine why this evidence was deemed to not be persuasive. The long-felt and unresolved need of neonatologists for the present invention is persuasive evidence of the nonobviousness of the claimed invention which must be considered by the Examiner.

Copying by Others

It came to the attention of the Applicant that at least one competitor has begun advertising the availability of a product that is a copy of the Applicant's invention. As noted on the attached advertisement, Hawaii Medical, LLC advertises the availability of a product called the TOOTSWEET™ 24% sucrose solution. The advertisement, among other things, states that this product ". . . helps to calm and soothe babies in distress and during painful procedures, while protecting against bacterial contamination." The prior art did not contemplate the Applicant's invention despite knowing about the benefits of sucrose since at least the late 80's (Blass article);

yet, within a few years of commercializing the Applicant's invention, a competitor copied the invention and began selling a competing product.

The evidence highlighting that at least one competitor has copied the Applicant's invention was submitted in the Response and Amendment filed on May 4, 2005. In the following office action, the Examiner did not specifically address the evidence of copying submitted by the Applicant. Instead, the Examiner stated that "[a]ll of applicant's remarks filed 5/4/05 have been fully and carefully considered but are not found convincing for the reasons of record which are considered to be clearly and fully detailed over the course of four Office actions." (Office Action of July 13, 2005 at p. 3, l. 21 – p. 4, l. 1.) It is not immediately apparent to the Applicant that this new evidence was considered or why the Examiner concluded that the evidence of copying by a competitor was not deemed persuasive. Evidence of copying by a competitor is persuasive evidence of nonobviousness that must be considered by the Examiner.

In summary, meeting anyone of the secondary considerations should be sufficient to support a conclusion that the present invention is nonobvious over the prior art. In this Application, the Applicant contends that it has met its burden by presenting evidence demonstrating not one but three of the secondary considerations. In the last Office Action, the Examiner stated that "[t]he secondary considerations were carefully considered but were not found to present any unexpected evidence, but instead presented evidence that would have been expected for one of ordinary skill in the art." (Office Action of March 13, 2006, p. 3, ll. 20-22.) The Applicant can find no authority that supports the conclusion that in addition to presenting evidence regarding secondary considerations, the Applicant must also demonstrate that the evidence is unexpected in order for the invention to be patentable. The Applicant has rebutted the Examiner's prima facie case with ample evidence that the present invention is nonobvious over the prior art of record. Accordingly, the pending claims are patentable over the prior art of record.

D. Conclusion

For the reasons set forth above, the rejections of the appealed claims are improper and should be reversed.

Respectfully submitted,

By _____

Timothy Nathan
Reg. No.: 44,256
Tel. No.: (724) 387-4435
Fax No.: (724) 387-5021

RESPIRONICS, INC.
1010 Murry Ridge Lane
Murrysville, PA 15668-8525

VIII. CLAIMS APPENDIX

1. A packaged solution for use in conjunction with a planned medical procedure on a neonatal infant, comprising:

a cup-shaped container having a greater width than a depth and defining a cavity therein opening to a mouth;

a volume of a solution comprising sucrose and water within the cavity, wherein the solution comprises about 10% to about 50% sucrose with a remainder of the solution comprising water; and

a cover disposed over the mouth and sealing the solution within the cavity;

wherein the solution and an interior of the container are in an aseptic state.

2. The packaged solution of claim 1, wherein the cover includes a lateral protrusion extending beyond a lateral extent of the cup shape of the container.

3. The packaged solution of claim 2, wherein the container includes a peripheral flange about the mouth, and the cover extends peripherally at least to an outer end of the peripheral flange.

4. The packaged solution of claim 3, wherein the peripheral flange includes a lateral protrusion and the lateral protrusion of the cover is substantially aligned therewith.

6. The packaged solution of claim 21, wherein the container includes a peripheral flange about the mouth, and the cover extends peripherally at least to an outer end of the peripheral flange.

7. The packaged solution of claim 6, wherein the cover is sealed to the peripheral flange.

10. The packaged solution of claim 1, wherein the solution comprises about 24% USP grade liquid sucrose to about 76% clean water.

12. A method for providing a solution for use in conjunction with a planned medical procedure on a neonatal infant, comprising:

preparing a solution comprising sucrose and water;

packaging the solution in single-use containers;

assembling a plurality of the single-use containers in a shipping container;

shipping the shipping container to an intended site of usage of the solution;

opening an individual, single-use container of the solution prior to the planned medical procedure;

administering a selected volume dose of the solution orally to the neonatal infant; and

discarding any residual solution within the opened, individual, single-use container after the planned medical procedure.

13. The method according to claim 12, further comprising maintaining the solution in each single-use container in an aseptic state after packaging until opening thereof for the planned medical procedure.

15. The method according to claim 12, further comprising formulating the solution to comprise between about 10% and about 50% sucrose with a remainder of the solution comprising water.

16. The method according to claim 12, further comprising formulating the solution to comprise about 24% USP grade liquid sucrose to 76% clean water.

17. A method of administering a solution to a neonatal infant, comprising:

providing a solution comprising sucrose and water in an aseptic state and in a volume selected for single patient use within a sealed container;

opening the container;

withdrawing a selected dose of the solution from the opened container and administering the selected dose of the solution to the neonatal infant; and

discarding any residual solution with the container.

19. The method of claim 17, further comprising providing the solution as between about 10% and about 50% sucrose with a remainder of the solution comprising water.

20. The method of claim 17, further comprising providing the solution as about 24% USP grade liquid sucrose to about 76% clean water.

21. The packaged solution of claim 1, wherein the cover is sealed to the container.

22. The method according to claim 12, further comprising packaging solution in cup-shaped, single use containers having covers sealed over the mouths thereof.

23. A packaged solution assembly for use in conjunction with a medical procedure performed on an infant, the solution being orally administered to the infant by a user, the packaged solution assembly comprising:

a cup-shaped container having a width and a depth, the width being greater than the depth and defining a cavity therein opening to a mouth, the cavity further defining an inner surface, the cup-shaped container also includes a flange extending outwardly about the mouth, the flange includes a top surface, the container is constructed from a polymeric material;

a volume of a solution comprising sucrose and water disposed within the cavity, the solution comprising approximately 24% sucrose and approximately 76% water; and

a cover disposed over the mouth and sealing the solution within the cavity, the cover sealingly engaging at least a portion of the top surface of the flange, the cover

further including a tab extending beyond the periphery of the flange such that the user can easily grasp and remove the cover.

24. The packaged solution assembly as recited in claim 23, wherein the cover is formed from a metal foil material.

25. The packaging solution assembly as recited in claim 23, wherein the cover is formed from a polymer film material.

26. The packaged solution assembly as recited in claim 23, wherein the cover is formed from a metallized insulating film.

27. The packaged solution assembly as recited in claim 23, wherein the peripheral flange includes a tab corresponding to the tab of cover.

28. The packaged solution assembly as recited in claim 23, wherein the solution and the interior of the container are in an aseptic state.

29. A packaged solution assembly for use in conjunction with a medical procedure performed on an infant, the solution being orally administered to the infant by a user via an object, the packaged solution assembly comprising:

a cup-shaped container having a width and a depth, the width being sized to receive at least a portion of an object, the cup-shaped container further includes a flange extending outwardly about the mouth, the flange provides a top surface;

a volume of a solution comprising sucrose and water disposed within the cavity, the solution comprises between approximately 10% and 50% sucrose in water; and

a cover disposed over the mouth and sealing the solution within the cavity, the cover sealingly engaging at least a portion of the top surface of the flange, the cover further including a tab extending beyond the periphery of the flange such that the user can easily grasp and remove the cover.

30. The packaged solution assembly as recited in claim 29, wherein the object is a pacifier.

31. The packaged solution assembly as recited in claim 29, wherein the object is a syringe.

32. The packaged solution assembly as recited in claim 29, wherein the cover is formed from a metal foil material.

33. The packaging solution assembly as recited in claim 29, wherein the cover is formed from a polymer film material.

34. The packaged solution assembly as recited in claim 29, wherein the cover is formed from a metallized insulating film.

35. The packaged solution assembly as recited in claim 29, wherein the peripheral flange includes a tab corresponding to the tab of cover.

36. The packaged solution assembly as recited in claim 29, wherein the solution comprises approximately 24% sucrose in water.

37. A method of producing a packaged solution assembly for use in conjunction with a medical procedure on an infant, the method comprising the steps of:

providing a cup-shaped container having a width and an depth, the width being sized to receive at least a portion of an object therein, the cup-shaped container defining a cavity therein opening to a mouth, the cup-shaped container further comprising a flange extending about the mouth of the cavity;

mixing between approximately 10% to 50% sucrose with water to create a sucrose solution;

transferring the sucrose solution into the cavity of the container; and

sealing the container with a cover that is placed over the mouth and sealed with the flange of the container.

38. The method as recited in claim 37, wherein the object is a pacifier.

39. The method as recited in claim 37, wherein the object is a syringe.

IX. EVIDENCE APPENDIX

The following evidence is submitted with this appeal:

Exhibit A – Marketing literature depicting the SWEET-EASE™ product sold by the Applicant, Respironics, Inc. This exhibit was submitted in the Applicant's Response and Amendment dated August 31, 2004.

Exhibit B – A declaration by Cathrine N. Bush under 37 C.F.R. § 1.132. This exhibit was submitted in the Applicant's Response and Amendment dated August 31, 2004.

Exhibit C – Declarations by Don T. Granger, M.D., Neal Guttenberg, M.D., and David Yohannan, M.D. This exhibit was submitted in the Applicant's Response and Amendment dated August 31, 2004.

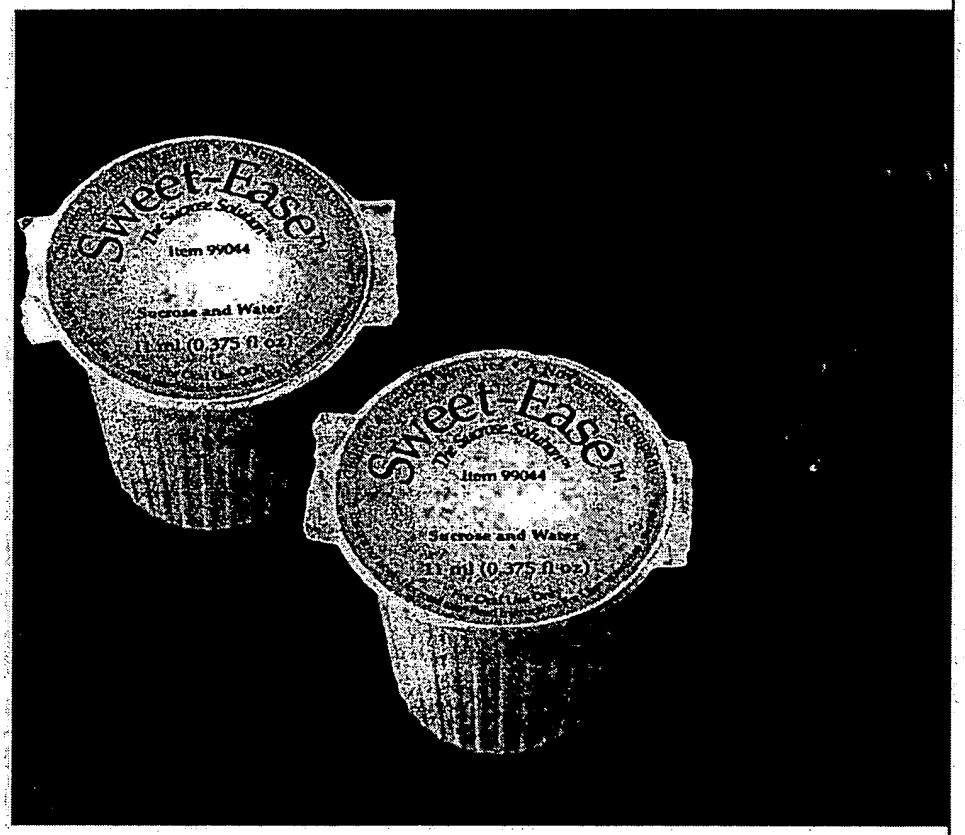
Exhibit D – Marketing literature depicting the TOOTSWEET™ product sold by a competitor, Hawaii Medical, LLC. This exhibit was submitted in the Applicant's Response and Amendment dated May 4, 2005.

EXHIBIT A

Children's Medical Ventures

Sweet-Ease™

The Sucrose Solution™



Features

- Provides a safe and convenient method for oral sucrose delivery
- 24% concentration level*
- Packaged aseptically
- Preservative free
- 11ml cup with peel off lid is suitable for dipping a pacifier or administration via a dropper
- 6 month shelf life

Benefits

- May be used in the NICU, PICU and Newborn Nursery
- Helps to calm and soothe babies in distress or during painful procedures *
- Aseptic packaging decreases risk of contamination
- Prepackaged solution prevents errors in preparation and saves time

1001 Murry Ridge Lane
Murrysville, PA 15668
www.childmed.com
www.respironics.com

* See bibliography on back.

MEDICAL DISPOSABLES

MEDICAL DISPOSABLES

Sweet-Ease™

The Sucrose Solution™

Specifications

- Ingredients: 24% sucrose, 76% water**
- 11ml of sucrose solution per cup
- Guaranteed aseptic in unopened, undamaged package
- Preservative free
- Packaged 200 cups per case (4 boxes of 50)
- Shelf life: six (6) months
- Latex free packaging

Precautions

- For oral use only (not for injection)
- For hospital use only
- Do not reuse or sterilize
- Store at 40°-90°F (4°-32°C)
- Dispose of product after use

**Over a six (6) month period, concentration may increase to 40%

Patent Pending

Instructions for Use

- Sweet-Ease™ should be used in compliance with standard hospital practices for oral sucrose delivery.
- See Instructions For Use in each 50 count box.

Bibliography

Barr RG., Quek VSH., Cousineau D., Oberlander TF, Brian JA., Young SN. Effects of Intra-Oral Sucrose on Crying, Mouthing and Hand-Mouth Contact in Newborn and Six-Week Old Infants. Developmental Medicine and Child Neurology. 1994, 36, 608-618.

Blass EM., Smith BA. Differential Effects of Sucrose, Fructose, Glucose, and Lactose on Crying in 1- to 3-Day-Old Human Infants: Qualitative and Quantitative Considerations. Developmental Psychology. 1992, Vol. 28, No.5, 804-810.

Smith BA., Fillion TJ., Blass EM. Orally Mediated Sources of Calming in 1- to 3-Day-Old Human Infants. Developmental Psychology. 1990, Vol. 26, No.5, 731-737.

Taylor S. Aseptic Cartons. Food Product Design: Focus On New Technologies. 1999.

Samples

Samples of Sweet-Ease™ are available. Please call Children's Medical Ventures at 800-345-6443 for further information.

Ordering Information

ITEM NO.	DESCRIPTION	QTY.
99044	Sweet-Ease™ The Sucrose Solution™	200/CS

TO ORDER

CALL 1-800-345-6443

or 1-724-387-4000

www.childmed.com

www.respironics.com

1001 Murry Ridge Lane

Murrysville, PA 15668

EXHIBIT B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

Inventor	:	DALY
Appln. No.	:	09/670,781
Conf. No.:	:	6751
Filed:	:	September 27, 2000
Title:	:	SYSTEM, METHOD AND PACKAGE FOR PROVIDING A LIQUID SOLUTIION
Group Art Unit	:	1761
Examiner	:	Weinstein, S.
Docket No.	:	00-39

* * * * *

August 27, 2004

DECLARATION OF CATHRINE N. BUSH

UNDER 37 C.F.R. § 1.132

Hon. Commissioner of Patents
and Trademarks
Alexandria, VA 22313-1504

Sir:

CATHERINE N. BUSH declares that:

1. I have been employed with Children's Medical Ventures, LLC (indirectly, a wholly owned subsidiary of Respironics, Inc.) ("CMV") since its inception in 1991. I am presently the Director of Strategic Marketing. When the SWEET-EASE ™ product was conceptualized and introduced to the market, I was the Vice President of Sales and Marketing. I was responsible for the product introduction, including marketing projections and sales/marketing tools.

2. I am familiar with the present U.S. Patent Application Serial No. 09/670,781 filed on September 27, 2000 entitled "System, Method and Package for Providing A Sucrose Solution."

3. The SWEET-EASE ™ product was introduced in the market in 2001. Since its introduction in 2001, the SWEET-EASE ™ product has experienced amazing success.

The market acceptance of the SWEET-EASE™ product has been surprising. In 2003, only 2 years after introduction, total sales were approximately 2.4 million cups for approximately $1.7 million in sales. This volume and adoption by the marketplace far exceeds both the typical growth of new products and our original expectations for this product.

4. For comparison purposes, CMV sells a heel warmer under the trademark HEEL HUGGER™. This product is used warm the sole of an infant's foot prior to a heel stick procedure. The HEEL HUGGER™ product has been in the marketplace for 5 years. In 2003, CMV sold approximately 400 thousand units. Therefore, in less than half the time, CMV has sold almost 6 times as many of the SWEET-EASE ™ product than of the HEEL HUGGER™ product.

5. I believe that these extraordinary sales results are because the SWEET-EASE™ product provides a convenient, aseptically packaged container filled with a sucrose solution not previously available in the medical industry. Research validating the effectiveness of sucrose to calm and soothe babies has been available since the late 1980's. However, because there was not a convenient, safe method for sucrose delivery, few hospitals were utilizing it even though it was shown to be effective.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above referenced Application of any patent issued therefrom.

Respectfully Submitted,

Catherine N. Bush

Catherine N. Bush

CATHERINE N. BUSH

Printed Name

8/28/04

Dated

EXHIBIT C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

Inventor	:	DALY
Appln. No.	:	09/670,781
Conf. No.:	:	6751
Filed:	:	September 27, 2000
Title:	:	SYSTEM, METHOD AND PACKAGE FOR PROVIDING A LIQUID SOLUTIION
Group Art Unit	:	1761
Examiner	:	Weinstein, S.
Docket No.	:	00-39

* * * * *

August 26, 2004

DECLARATION OF DON T. GRANGER, M.D.

UNDER 37 C.F.R. § 1.132

Hon. Commissioner of Patents
and Trademarks
Alexandria, VA 22313-1504

Sir:

Don T. Granger, M.D. declares that:

1. I am a board-certified neonatologist and work in the Newborn Intensive Care Unit ("NICU") at the Children's Medical Center in Dayton, Ohio. The NICU at the Children's Medical Center is a 31-bed intensive care unit for high-risk newborns having medical or surgical problems.

2. The newborns admitted to the NICU are often very sick and require many painful or uncomfortable procedures. They may require blood to be drawn, venipunctures, IV starts, dressing changes, and catheter insertions. For some, these procedures may need to be performed multiple times every day.

3. I am familiar with the SWEET-EASE ™ product sold by Respironics, Inc. and have personally seen its commercial success in the marketplace.
4. I have personally seen sick newborns with elevated heart and breathing rates as a result of performing a procedure. I have also witnessed newborns that become unsettled and cry or vomit immediately following a procedure.

EXHIBIT C

5. Before the SWEET-EASE ™ product was available, I, or an attending nurse, would attempt to console the newborn by rocking or patting, if feasible. However, many sick newborns under our care are in incubators, have been intubated, or for other reasons cannot be moved or picked up. Calming these newborns becomes quite difficult.

6. It is known that oral administration of a sucrose solution can calm and sooth newborns. However, manually mixing a sucrose solution could prove dangerous and even life threatening to these sick newborns since it would be difficult to properly sterilize the mixture. For this reason, I am unwilling to personally mix a sucrose solution or to instruct others to do so.

7. There has long been a definite need in our industry for some way to calm and sooth these newborns. I have personally longed for some way to ease these newborn's suffering and discomfort. The SWEET-EASE ™ product meets this need.

8. I have personally witnessed the administration of the SWEET-EASE ™ product to newborns before receiving a procedure. These newborns are much less distressed. The results have exceeded my expectations. Although I expected some calming effect, the degree of effectiveness I witnessed was unexpected. In some cases, I have seen newborns quietly lay still during a procedure following the administration of the SWEET-EASE ™ product.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above referenced Application of any patent issued therefrom.

Respectfully Submitted,

Don T Granger MD

Don T. Granger, M.D.

8-26-04

Dated

EXHIBIT C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

Inventor	:	DALY
Appln. No.	:	09/670,781
Conf. No.:	:	6751
Filed:	:	September 27, 2000
Title:	:	SYSTEM, METHOD AND PACKAGE FOR PROVIDING A LIQUID SOLUTIION
Group Art Unit	:	1761
Examiner	:	Weinstein, S.
Docket No.	:	00-39

* * * * *

August 26, 2004

DECLARATION OF NEAL GUTTENBERG, M.D.

UNDER 37 C.F.R. § 1.132

Hon. Commissioner of Patents
and Trademarks
Alexandria, VA 22313-1504

Sir:

Neal Guttenberg, M.D. declares that:

1. I am a board-certified neonatologist and work in the Newborn Intensive Care Unit ("NICU") at the Children's Medical Center in Dayton, Ohio. The NICU at the Children's Medical Center is a 31-bed intensive care unit for high-risk newborns having medical or surgical problems.

2. The newborns admitted to the NICU are often very sick and require many painful or uncomfortable procedures. They may require blood to be drawn, venipunctures, IV starts, dressing changes, and catheter insertions. For some, these procedures may need to be performed multiple times every day.

3. I am familiar with the SWEET-EASE ™ product sold by Respironics, Inc. and have personally seen its commercial success in the marketplace.
4. I have personally seen sick newborns with elevated heart and breathing rates as a result of performing a procedure. I have also witnessed newborns that become unsettled and cry or vomit immediately following a procedure.

EXHIBIT C

5. Before the SWEET-EASE ™ product was available, I, or an attending nurse, would attempt to console the newborn by rocking or patting, if feasible. However, many sick newborns under our care are in incubators, have been intubated, or for other reasons cannot be moved or picked up. Calming these newborns becomes quite difficult.

6. It is known that oral administration of a sucrose solution can calm and sooth newborns. However, manually mixing a sucrose solution could prove dangerous and even life threatening to these sick newborns since it would be difficult to properly sterilize the mixture. For this reason, I am unwilling to personally mix a sucrose solution or to instruct others to do so.

7. There has long been a definite need in our industry for some way to calm and sooth these newborns. I have personally longed for some way to ease these newborn's suffering and discomfort. The SWEET-EASE ™ product meets this need.

8. I have personally witnessed the administration of the SWEET-EASE ™ product to newborns before receiving a procedure. These newborns are much less distressed. The results have exceeded my expectations. Although I expected some calming effect, the degree of effectiveness I witnessed was unexpected. In some cases, I have seen newborns quietly lay still during a procedure following the administration of the SWEET-EASE ™ product.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above referenced Application of any patent issued therefrom.

Respectfully Submitted,

Neal Guttenberg

Neal Guttenberg, M.D.

8/26/04

Dated

EXHIBIT C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

Inventor	:	DALY
Appln. No.	:	09/670,781
Conf. No.:	:	6751
Filed:	:	September 27, 2000
Title:	:	SYSTEM, METHOD AND PACKAGE FOR PROVIDING A LIQUID SOLUTIION
Group Art Unit	:	1761
Examiner	:	Weinstein, S.
Docket No.	:	00-39

* * * * *

August 26, 2004

DECLARATION OF M. DAVID YOHANNAN, M.D.

UNDER 37 C.F.R. § 1.132

Hon. Commissioner of Patents
and Trademarks
Alexandria, VA 22313-1504

Sir:

M. David Yohannan, M.D. declares that:

1. I am a board-certified neonatologist and work in the Newborn Intensive Care Unit ("NICU") at the Children's Medical Center in Dayton, Ohio. The NICU at the Children's Medical Center is a 31-bed intensive care unit for high-risk newborns having medical or surgical problems.

2. The newborns admitted to the NICU are often very sick and require many painful or uncomfortable procedures. They may require blood to be drawn, venipunctures, IV starts, dressing changes, and catheter insertions. For some, these procedures may need to be performed multiple times every day.

3. I am familiar with the SWEET-EASE ™ product sold by Respironics, Inc. and have personally seen its commercial success in the marketplace.
4. I have personally seen sick newborns with elevated heart and breathing rates as a result of performing a procedure. I have also witnessed newborns that become unsettled and cry or vomit immediately following a procedure.

EXHIBIT C

5. Before the SWEET-EASE ™ product was available, I, or an attending nurse, would attempt to console the newborn by rocking or patting, if feasible. However, many sick newborns under our care are in incubators, have been intubated, or for other reasons cannot be moved or picked up. Calming these newborns becomes quite difficult.

6. It is known that oral administration of a sucrose solution can calm and sooth newborns. However, manually mixing a sucrose solution could prove dangerous and even life threatening to these sick newborns since it would be difficult to properly sterilize the mixture. For this reason, I am unwilling to personally mix a sucrose solution or to instruct others to do so.

7. There has long been a definite need in our industry for some way to calm and sooth these newborns. I have personally longed for some way to ease these newborn's suffering and discomfort. The SWEET-EASE ™ product meets this need.

8. I have personally witnessed the administration of the SWEET-EASE ™ product to newborns before receiving a procedure. These newborns are much less distressed. The results have exceeded my expectations. Although I expected some calming effect, the degree of effectiveness I witnessed was unexpected. In some cases, I have seen newborns quietly lay still during a procedure following the administration of the SWEET-EASE ™ product.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above referenced Application of any patent issued therefrom.

Respectfully Submitted,

M. David Yohannan, M.D.

8-27-2004

Dated

EXHIBIT D

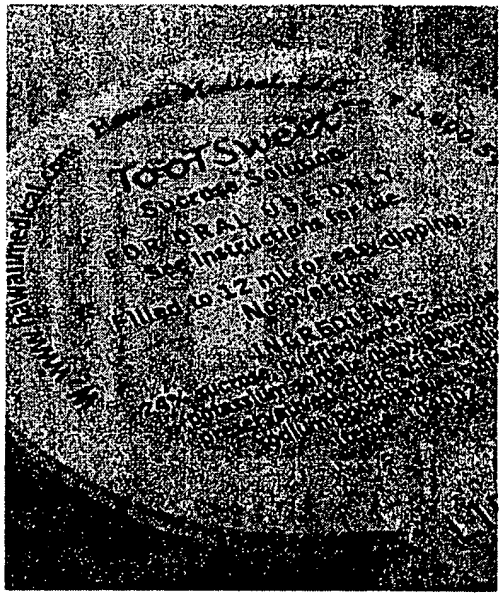
Hawaii Medical

TootSweet™

24% Sucrose Solution

Economical and Convenient...TWO-Year Shelf Life!

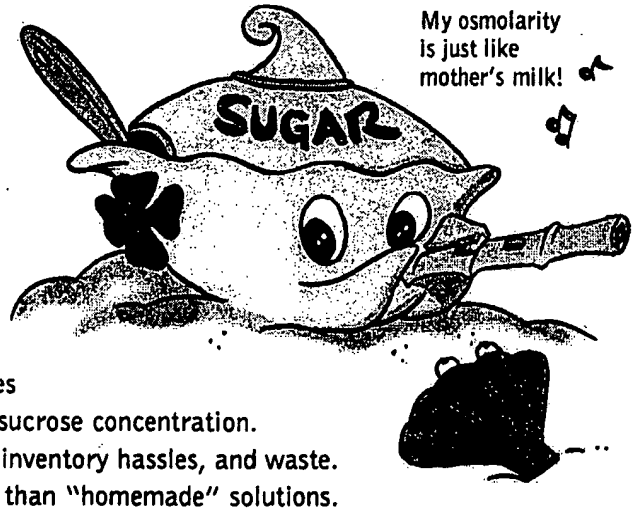
- Economical and easy to use
- No refrigeration required
- Easy pacifier dipping – no tipping
- Stable container materials prevent changes in sucrose concentration
- Two-year shelf life



THE LARGE TOOTSWEET CUP ALLOWS EASY DIPPING OF OUR GUMDROP PACIFIER. PLENTY OF EXCESS SPACE ELIMINATES OVERFLOW.

Now there's a safe, convenient way to deliver sucrose solution to your babies – *TootSweet*™ 24% sucrose solution. TootSweet helps calm and soothe babies in distress and during painful procedures, while protecting against bacterial contamination.

- For preemie and full-term babies.
- Baby-appropriate preservatives prevent bacterial growth.
- Osmolarity buffered to range of mother's milk (260 mOsm/kg).
- 12 ml in a 30 ml cup. Single patient use.
- Large cup for easy pacifier dipping or transfer into an oral syringe for dose splitting (single patient use only) without spills.
- Stable container material keeps formulation consistent, eliminates evaporation, prevents increased sucrose concentration.
- Two-year shelf life reduces cost, inventory hassles, and waste.
- More economical and consistent than "homemade" solutions.



TootSweet™

EXHIBIT D

Keep Babies Safe and Save Your Hospital Money with Easy-to-Use TootSweet™!

Sucrose is a proven, effective method of helping to calm and soothe babies. It is also an ideal medium to grow bugs! Contamination can occur from airborne bacteria, contact with oral flora from re-dipped pacifiers or mucosal contact with oral syringes. Independent studies found non-preserved 24% sucrose became highly contaminated (53 large colonies, and small colonies too numerous to count) with bacteria and mold in a matter of hours after contact with a pacifier used by an infant. (Copy of report available on request.)

TootSweet's Baby-Appropriate Preservatives Prevent Bacterial Growth and Extend Shelf Life.

TootSweet is preserved with methylparben and potassium sorbate, preservatives in Ora-Sweet™, Gentamicin, Caffeine Citrate, and other products commonly administered to preemies and full-term babies. So you can have confidence TootSweet is safe, whether you administer it by dose-splitting in oral syringes, or when using a pacifier. We tested our formulation in accordance with USP Preservative Effectiveness Test (27 NF 22 2004). ISO certified Toxikon Testing Laboratory separately inoculated 20ml aliquots of TootSweet with 1.0 x 106 of the following organisms: Aspergillus nigar, Candida albicans, Escherichia coli, Pseudomonas aeruginos and Staphylococcus aureus. The test results met current USP criteria for Antimicrobial Preservative Effectiveness Test.

Instructions for Use

TootSweet has a two-year shelf life in un-opened containers. TootSweet is single patient use. TootSweet may be administered by ORAL only syringe (label appropriately), or by pacifier dipping. And remember, always follow your hospital protocols for sucrose use. Just a couple of drops on a pacifier or on the tip of the tongue, a few minutes before a procedure, is sufficient.

PRODUCT SPECIFICATIONS:
1 oz cup containing 12ml of 24% sucrose in purified water.
0.022% methylparben and 0.073% potassium sorbate as preservatives.
Citric acid and dibasic sodium phosphate as buffers to adjust osmolarity.

Ordering Information

Give your babies the comfort and convenience of TootSweet! To place an order, request a sample, or find out more, please call Tri-anim, our national distributor at 1.800.874-2646.

TootSweet 24% Sucrose Solution

ITEM #	DESCRIPTION	QUANTITY
1040021	1oz cups with 12ml 24% sucrose solution	Box of 40
1040022	1oz cups with 12ml 24% sucrose solution	Case of 240 (6 boxes)

Other Great NICU Solutions from Hawaii Medical

- *GumDrop Pacifier™*
  Incredibly soft! Silicone covers entire surface. Low profile design. No trimming to fit nasal tubes!
- *LifeGuard™ Electrodes*
  Electrodes that last, even in high humidity incubators.
- *LilyPad™ Pressure Relieving Mattress*
  Keeps babies more comfortable. Economical. Clean and re-use. Doesn't stain!

- *NeatNick™*
  Sweeping action heel lancet makes a neater nick. Is less painful for your babies. Costs less, too!
- *Save the Gonads™ X-Ray Shields*
  The first x-ray shields designed for babies, from micro-preemies to full-term newborns.
- *Shell-O™ Gel Pillow and Positioning Aid*
  Affordable, long-lasting gel support for babies of all sizes.
- *SunFish™ Locking Temp Probe Cover*
  Designed to lock the temp probe wire in place.

Call for Product Samples or More Information

Hawaii Medical products are available for order from our national distributor, Tri-anim. For questions, product samples, or the sales representative in your area, please call 1.800.874.2646.

Aloha from Boston!

Hawaii Medical
Innovating Medical Products For Kids

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Tel 1.800.596.1555 Fax 781.826.2544
Web www.hawaiimedical.com

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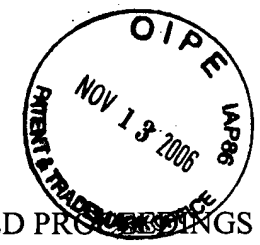

X. RELATED PROCEEDINGS APPENDIX

There are no related decisions rendered by a court or by the Board.